

AO 91 (Rev. 11/11) Criminal Complaint

CLERK'S OFFICE U.S. DIST. COURT
AT ABINGDON, VA

FILED

UNITED STATES DISTRICT COURT

FEB 14 2020

for the

Western District of Virginia

JULIA C. DUDLEY, CLERK
BY: *[Signature]*
DEPUTY CLERK

United States of America

v.

Jeffery Leedy

Case No. 1:20mj22

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of November 2018 to June 2019 in the county of Roanoke in the
Western District of Virginia, the defendant(s) violated:*Code Section*
18 USC §.1365*Offense Description*
Tampering with a Drug

This criminal complaint is based on these facts:

See Attached Affidavit

☒ Continued on the attached sheet.*Complainant's signature*

Darren Petri, Special Agent

Printed name and title

Sworn to before me and signed in my presence.

Date:

2/14/20

City and state:

Abingdon, VA*Judge's signature*

Pamela Sargent, U.S. Magistrate Judge

Printed name and title

AFFIDAVIT

I, Darren Petri, Special Agent for the Food and Drug Administration, Office of Criminal Investigation (FDA/OCI), being duly sworn, depose and state as follows:

I am a Special Agent with the FDA/OCI, assigned to the Washington Metro Field Office. Prior to my current assignment, I was employed by the Department of Veterans Affairs, Office of Inspector General, Criminal Investigation Division, assigned to the Washington Field Office, Washington, D.C. I worked there from April 2006 to February 2013. Previously, I was employed by the FDA/OCI and worked there from March 2004 to April 2006. Prior to my employment with the FDA/OCI, I worked for the United States Army Criminal Investigation Command (USACIDC), Major Procurement Fraud Unit, Ft. Belvoir, Virginia, from September 2002 to March 2004, as a Special Agent investigating white collar fraud. Before working with the USACIDC, I was employed by the Harnett County Sheriff's Office (HCSO), Harnett County, North Carolina, from August 2001 to September 2002, where I was assigned as a detective investigating economic crimes and general criminal offenses. Prior to my employment with the HCSO, I worked for the USACIDC, from August 1995 to August 2001, where I investigated economic crimes, general crimes, and drug crimes. During my 25 years of investigative experience, I have dealt with violations of the Uniform Code of Military Justice, the North Carolina General Statutes, and Titles 18 and 21 of the United States Code. I also have drafted and served a number of search warrants and arrest warrants authorized by local, state, and federal judges. In my current position with the FDA/OCI, I investigate violations of federal laws including the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21, U.S. Code, Sections 301 – 397, and Title 18 of the United States Code. Based on my training and experience, I am

familiar with the rules and regulations governing the drug approval process, methods used to commit fraud against the U.S. Government, and documents and other records that frequently are evidence of such fraud.

During my time as a Special Agent, I have completed specialized training courses at the Department of Homeland Security's Federal Law Enforcement Training Center, the North Carolina Justice Academy, and the USACIDC training facilities. I also have participated in numerous investigations that have resulted in the seizure of evidence, including illegal drugs and documents.

The facts and information contained in this affidavit are based upon my training and experience, participation in investigations, personal knowledge, and observations during the course of this investigation, as well as the observations of other agents involved in this investigation. All observations not personally made by me were relayed to me by the individuals who made them or are based on my review of records, documents, and other physical evidence obtained during the course of this investigation.

This affidavit contains information necessary to support probable cause. It is not intended to include every fact and matter observed by me or known to the United States.

RELEVANT FEDERAL LAW

18 USC § 1365, Tampering - Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury (the term “bodily injury” includes physical pain, or any other injury to the body, no matter how temporary), tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall be guilty of an offense.

INTRODUCTION

Based on the information set forth below, your affiant submits that there is probable cause to believe that between November 2018 to June 2019, in the Western District of Virginia, Jeffery Leedy committed the offense of Tampering, when Leedy knowingly and willingly diverted and tampered with over 53 vials of Fentanyl in medication vials intended for the use of patients in and around the Roanoke, VA area.

DETAILS

In May 2019, this investigation was initiated when J.A., a former Pharmacy Supervisor, Lewis Gale Hospital (LGH), Salem, VA, explained that he was in possession of a suspected tampered vial of fentanyl after receiving it from P.B., a Roanoke City Emergency Management Services (RCEMS) ambulance crew member. P.B. told J.A. that he discovered the suspected tampered vial of fentanyl when he was on an emergency medical services (EMS) call and attempted to administer the vial to a patient. P.B. noticed that the cap was not secured on the vial and believed that the vial may have been tampered with. P.B. then grabbed a different vial of

fentanyl and administered that vial to the patient. The suspected tampered vial of fentanyl was then set off to the side and later given to J.A.

J.A. tested the vial of fentanyl by using a light refractometer and determined that the vial was tampered with. J.A. also noticed several puncture marks in the stopper of the vial. J.A. secured the vial of fentanyl and then later provided it to investigators.

On May 28, 2019, SAs Darren Petri and Aaron Valley, Virginia State Police (VSP) coordinated this investigation with C.C., Education Program Director, Western Virginia Emergency Management Services (WVEMS) and G.D., Field Coordinator, WVEMS, at which time they provided information about the previously mentioned tampered vial of fentanyl. C.C. and G.D. said that the WVEMS is a branch of the Virginia Department of Health and covers several counties in the Western part of Virginia which surrounds the Roanoke Valley. WVEMS regulates the Advanced Life Support (ALS) certificates for ambulance services and provides the licensed ambulance services in their area with drug/narcotics boxes. These boxes are not stocked with drugs by the WVEMS, but rather the supporting hospitals in the respective areas. Each box has a control number and is tracked by that unique number by the hospitals. Within the box (Orange drug box) there is a smaller secured box (Yellow box) that houses the controlled medications, including fentanyl. The WVEMS has a list of drugs approved for 2019 that are allowed to be stocked in the Orange drug box and the Yellow box. At the time there was only a few drugs approved for the secured Yellow box; fentanyl, ketamine, hydromorphone, and midazolam. When an ambulance in the field uses any of the drugs from the Orange and/or Yellow boxes, the boxes are turned in to the hospital where the patient is dropped off. The

hospital will then provide the ambulance with a box that was previously stocked by the hospital pharmacy and take the used box and provide it to the pharmacy for restocking. Referring to the paperwork that documents the Orange/Yellow box exchange concerning the tampered fentanyl, the box in question that contained the tampered fentanyl was EMS box #3073 and the new box received by the ambulance was EMS box #1488. The individual/ambulance employee who reported the tampering and first noticed the tampered vial in the field was P.B. (previously mentioned). P.B. noticed the tampered vial of fentanyl on May 16, 2019. C.C. and G.D. also said that they were contacted a few weeks prior about another diversion/tampering of an EMS box from Carilion Clinics, Roanoke, VA.

On May 28, 2019, SAs Petri and Valley coordinated with T.A., Director of Pharmacy, Lewis Gale Hospital (LGH), Salem, VA, at which time he provided further information about the suspected tampering of a fentanyl vial from LGH. T.A. provided paperwork for EMS box #3073 with the tampered vial of fentanyl and when it was filled at the hospital.

On June 4, 2019, SA Valley coordinated this investigation with SA Jason Trent, VSP, who provided information about this case. SA Trent said that he was notified of a diversion/tampering that occurred at the Central Lynchburg General Hospital (CLGH), Lynchburg, VA. SA Trent said that the individual responsible for the diversion/tampering was Jeffery Leedy. Leedy was a part-time EMS worker at the hospital and also worked as an EMS employee for Roanoke County. Leedy tested positive for fentanyl after he was caught taking fentanyl vials from the excess containers. He was removed from the hospital for suspicion of diversion/tampering with fentanyl.

On June 4, 2019, SA Valley spoke to S.S., Supervisor/Fire Chief for Roanoke County EMS, at which time he queried the access card database for Leedy and determined that Leedy had been accessing rescue squad buildings at night while he was not working. Simons related that he would provide a list of all the card entries concerning Leedy. S.S. said that Leedy worked part-time as an EMS employee at the Read Mountain Fire and Rescue Department, 43 Eastpark Dr, Roanoke, VA. On November 25, 2019, SA Petri received the door access spreadsheet from the Roanoke County EMS, which depicted that Leedy accessed EMS facilities from August 1, 2018 to June 4, 2019. The following facilities were accessed Catawba, Bent Mountain, Read Mountain, Fort Lewis, and Back Creek. The facility that was mainly accessed by Leedy was Read Mountain, which Leedy did not mention during his interview, dated August 8, 2019.

On June 10, 2019, SA Valley explained to your affiant that he met with T.A. who provided 22 vials of suspected tampered medications to include 20 vials of fentanyl and 2 vials of morphine. The 22 vials came from 8 different EMS Orange boxes #: 1487, 1151, 1306, 1003, 1062, 1006, 1013, and 1409. The lot numbers for the vials were as follows:

West Ward - 038317 (morphine), 038304 (fentanyl), 068309 (fentanyl),
058320 (fentanyl), 018310 (morphine), 088303 (fentanyl), 088303 (fentanyl), and
117301 (fentanyl).

Hospira - 94-466-DK (fentanyl), 94-466-DK (fentanyl), 94-466-DK (fentanyl), 96-164-DK (fentanyl), 02-262-DK (fentanyl), 03-110-DK (fentanyl), 94-406-DK (fentanyl), 91-080-DK (fentanyl), 94-406-DK (fentanyl), 01-397-DK (fentanyl), 95-170-DK (fentanyl), 01-395-DK (fentanyl), 91-080-DK (fentanyl), and 93-087-DK (fentanyl).

On June 11, 2019, SAs Petri and Valley interviewed C.A., Roanoke County Fire and Rescue (RCFR), who provided information pertaining to this investigation. On Tuesday, June 4, 2019, C.A. said that she saw that Leedy was not on the schedule to work and sent him a text on his cell phone asking what had happened. Leedy replied in a group text to C.A., M.A., and T.R., all friends of Leedy from work (RCFR). As a result of the group text, they all agreed to meet that evening at a restaurant to further discuss what had happened to Leedy. Leedy told them that he was suspended from his job at CLGH because of his aggressiveness as a medic and his narcotic use. He also told them that he came back positive on a drug test for fentanyl. He explained to C.A., M.A. and T.R. that he was an addict who was addicted to fentanyl. Leedy said that he was taking the remaining amount of fentanyl from the vials that he administered to patients for himself and then filling the vials with saline. The vials were then placed back into the EMS boxes.

On June 11, 2019, SAs Petri and Valley interviewed M.A., who provided information pertaining to this investigation. On Tuesday, June 4, 2019, M.A. said that he received a group text from Leedy, which included C.A. and T.R. on the text. M.A. knows Leedy from RCFR and is work friends with T.R. as well. On the evening of June 4, 2019, around 7:30pm they met at a

restaurant, ate dinner and Leedy explained what happened at work. Leedy told them that he was suspended from his job at CLGH because of his aggressiveness as a medic and his narcotic use. He also told them that he came back positive on a drug test for fentanyl. Leedy said that he was taking the fentanyl from patient's vials and filling the vials with saline. The vials were then placed back into the EMS boxes.

On June 11, 2019, SAs Petri and Valley interviewed T.R., who provided information pertaining to this investigation. On Tuesday, June 4, 2019, T.R. said that he received a group text from Leedy. Also on the group text were C.A. and M.A. The four of them are all friends from RCFR. That same day around 7:30pm they met at a restaurant, ate dinner and Leedy told them what occurred. Leedy told them that he was suspended from his job at CLGH because he tested positive for fentanyl. He worked at both CLGH and RCFR until May 1, 2019, when he was fired from CLGH. He explained to everyone that he was an addict who was addicted to fentanyl. Leedy told them that he would fill a syringe with fentanyl and bring it home to his address in Roanoke, VA. T.R. said that Leedy had access to saline from the EMS truck where they worked. While Leedy was home he would inject himself and get high from the fentanyl. Leedy told T.R. that he was cutting the tags that secured the EMS boxes because it made it easier for him to remove the tag when he needed a drug in the field. T.R. said that it was significant because the tag could be backed out and the narcotics box accessed without breaking the tag seal. T.R. thought he saw Leedy drop something drug related into the tactical bag Leedy always carried. As a result, T.R. searched through Leedy's bag. When T.R. quickly went through the bag, he thought he noticed a small tube of glue.

On June 12, 2019, SA Petri received from SA Valley information concerning Leedy's time as a CLGH employee. The information consists of the following documents: A statement from an employee, wherein they received one transport bag on April 27, 2019, and one transport bag on April 28, 2019, from Leedy with tampered fentanyl in them; summaries of conversations between the supervisor for transport and Leedy, on April 29, 2019, April 30, 2019 and May 6, 2019, wherein they discussed mandatory drug testing; conversations with the supervisor for transportation, regarding a second hair sample from Leedy; prescription history of Leedy, which depicts prescriptions for oxycodone-acetaminophen 10-325 mg and hydrocodone-acetaminophen 5-325 mg on a regular basis from July 5, 2017, to January 3, 2019; and a spreadsheet from CLGH depicting the tampered with medications handled by Leedy from April 15, 2019, to April 29, 2019.

On June 20, 2019, SA Valley explained to your affiant that he met with T.A. and N.G., Director of Pharmacy, CLGH, who provided several items of evidence to include the following: 9 vials of suspected tampered fentanyl and 2 vials of suspected tampered hydromorphone from CLGH and 6 vials of suspected tampered drug from LGH. The lot numbers for the vials were as follows:

West Ward 5ml fentanyl, lot number 088357/AP10-1; EMS bag #10.

West Ward 5ml fentanyl, lot number 028341/AP10-2; EMS bag #10.

West Ward 5ml fentanyl, lot number 088357/AP10-3; EMS bag #10.

West Ward 2ml hydromorphone, lot number 078359/AP10-4; EMS bag #10.

West Ward 5ml fentanyl, lot number 028341/AP3-1; EMS bag #3.

West Ward 5ml fentanyl, lot number 028341/AP3-2; EMS bag #3.

West Ward 2ml hydromorphone, lot number 038349/AP3-3; EMS bag #3.

West Ward 5ml fentanyl, lot number 028345/AP5-1; EMS bag #5.

West Ward 5ml fentanyl, lot number 028345/AP5-2; EMS bag #5.

West Ward 5ml fentanyl, lot number 088357/AP5-3; EMS bag #5.

West Ward 5ml fentanyl, lot number 028345/AP-12; EMS bag #12.

Hospira 5ml fentanyl (control vial), lot number 93-501-DK.

West Ward 2ml fentanyl, lot number 098411; EMS Orange box #1268.

Hospira 2ml fentanyl, lot number 95-170-DK; EMS Orange box #1268.

Hospira 2ml fentanyl, lot number 95-170-DK; EMS Orange box #1086.

Hospira 2ml fentanyl, lot number 94-466-DK; EMS Orange box #1086

West Ward 2ml fentanyl, lot number 048312; EMS Orange box #1086.

On August 8, 2019, SAs Petri and Valley interviewed Jeffery Leedy, while at his residence in Roanoke, VA. Leedy admitted to the diversion and tampering of fentanyl vials from the several locations in and around the Roanoke, VA area. From November 2018 to June 2019, Leedy was involved in diverting and tampering medications while employed in two hospitals and the Roanoke County EMS. The first place he began diverting medications was when he worked at the Lewis Gale Hospital (LGH) in Salem, VA. He was fired from that job and began working at Central Lynchburg General Hospital (CLGH) in Lynchburg, VA. During the last few months before he sought help in June 2019, he diverted and tampered fentanyl and hydromorphone while working at CLGH and Roanoke County EMS, which serves several hospitals in the Roanoke, VA area.

He began diverting and tampering medications by taking the waste from patients while on EMS runs at LGH and CLGH. While he was working at CLGH he obtained the saline to put in the vials of medications from the hospital EMS trucks. At CLGH the medication bags used by healthcare providers had both fentanyl and saline that he used for the tampering. The hydromorphone he tampered with was also in the medication bags. Leedy explained he would pull out the fentanyl after the calls he went on and put the saline in its place. Leedy would keep superglue in his black tactical bag that he kept on his person and used it to fix the caps back onto the vials of fentanyl. After he removed the fentanyl and replaced it with saline, he would place the vials back in the EMS box and return the box to the hospitals for the next ambulance crew to pick up and use.

While working at the Roanoke County EMS, Leedy would go into the Catawba and Bent Mountain locations to access the EMS boxes in order to tamper with vials of fentanyl. He would go into these locations late at night when the daytime shift left for the day and no one was around. Leedy began going into the EMS locations sometime around May 2019 in order to pull the fentanyl from the vials and put the saline in its place. Leedy said that he was fired from the Roanoke County EMS in late May 2019 and entered into rehab on June 5, 2019. Leedy was asked if there were anymore vials of fentanyl, other than the more than 50 vials that SAs Petri and Valley discovered during the course of this investigation, that he tampered with. Leedy was not shown any specific vial or provided with any numbers that would single out any one vial of fentanyl that was collected as evidence during the course of this investigation. Leedy said that he only tampered with the number of vials that was discovered throughout this investigation.

On August 23, 2019, SA Petri collected 8 vials of suspected tampered fentanyl from M.Y., Pharmacy Manager, Carilion Clinics, Roanoke, VA. The vials came from EMS box #'s 1143, 1379, 3095, 1320, and 1393. SA Petri was also provided with the drug box forms that depicted the patient's name, EMS box number and EMS representative that turned the box in to the pharmacy for refill. Also provided was a note written by T.L., a paramedic for Roanoke City Fire and EMS. The note read that on June 13, 2019, he attempted to administer fentanyl to a patient, but the needle was unable to pierce the seal of the rubber stopper of the vial. This resulted in the rubber stopper being pushed into the vial and the fentanyl spilling. The fentanyl came from EMS box #1393.

On August 23, 2019, SA Petri collected 9 vials of suspected tampered fentanyl from E.C., Pharmacy Manager, LGH. The vials came from EMS box #'s 1128, 3063, 3087, 1280, and 1124.

On September 27, 2019, SA Petri and SA Valley coordinated with E.C. and T.A., at which time they provided further information concerning this investigation. E.C. related that the LGH pharmacy received a phone call in April 2019, from L.M., a pharmacy employee at Carilion Clinics, Roanoke, VA, who asked if they had a fentanyl vial from an EMS box Carilion had in their possession. L.M. explained that the EMS box was missing three fentanyl vials in all. In May 2019, T.A. saw Leedy, in an official capacity, leave with two EMS boxes from LGH. T.A. grew suspicious of Leedy, due to his previous interactions with him at LGH. Leedy was previously fired from LGH for going through sharps containers and administering drugs outside of his practice as an EMS employee. Sometime after that, an EMS employee came to the

pharmacy and informed them of a vial that had a rubber stopper that fell off of a vial of fentanyl. They conducted a visual examination, tested the fentanyl and noticed superglue on the vial. They previously provided the vial to SAs Petri and Valley for examination. Notes were kept of the tampered vials of fentanyl after they noticed Leedy still working as an EMS employee and walking out with the EMS boxes from the hospital. The notes were as follows:

- Box #1062, June 4, 2019, had three vials of Hospira fentanyl with puncture marks in the stoppers. The EMS box had a short tag sealing the vials.
- Box #1003, June 4, 2019, had one vial of Hospira fentanyl with puncture marks in the stopper. The EMS box was last turned over on June 1, 2019, and two fentanyl vials were replaced by LGH.
- Box #1006, June 4, 2019, had three tampered vials of fentanyl and one tampered vial of morphine with a hair under the glued cap. The EMS box had a short tag sealing the vials.
- Box #1013, brought in to LGH with suspicions of tampering of three vials of fentanyl. Two of the vials had glued caps on the vials and the third had visible puncture marks in the cap.
- Box #1059, brought in to LGH with no vials of fentanyl in the EMS box and a short tag sealing the box. Agent's Note: Every EMS box has three vials of fentanyl at all times.
- Box #1086, three vials of fentanyl that had signs of tampering.
- Box #1151, June 4, 2019, three vials of fentanyl that had signs of tampering.
- Box #1229, had no fentanyl vials in the EMS box.
- Box #1487, June 4, 2019, had one tampered vial of morphine and one tampered

vial of fentanyl.

ORIGIN OF FENTANYL

SA Petri coordinated with Melissa Yabro, Pharmacy Manager, Pharmacy Department at Carilion Hospital, Roanoke, VA, who provided the only four authorized injectable Fentanyl manufactures in the U.S. as Hikma Pharmaceuticals, Hospira Inc, Akorn Inc, and Fresenius Kabi AG (SA Petri called and confirmed with each of the pharmaceutical companies that the locations provided below were correct):

West Ward fentanyl is manufactured by Hikma Pharmaceuticals USA Inc, which is produced in Cherry Hill, NJ and shipped throughout the U.S.

Hospira fentanyl is manufactured by Hospira Inc., which is produced in Lake Forest, IL and shipped throughout the U.S.

Akorn fentanyl is manufactured by Akorn Inc., which is produced in Decatur, IL and shipped throughout the U.S.

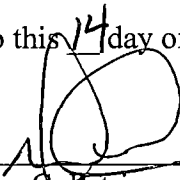
Fresenius Kabi fentanyl is manufactured by Fresenius Kabi AG, which is produced in Grand Island, NY and shipped throughout the U.S.

As set forth above, vials of fentanyl available for use by the EMS personnel in the Roanoke, VA area, are only manufactured outside of Virginia. Accordingly, any tampering with those vials by Leedy would be affecting Interstate Commerce.

CONCLUSION

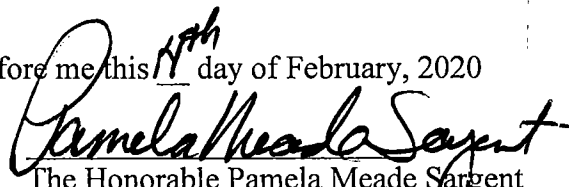
Based on the above described facts and circumstances and your affiant's training, knowledge and experience, there is probable cause to believe that between November 2018 to June 2019, in the Western District of Virginia, Jeffery Leedy committed the offense of Tampering, when Leedy knowingly and willingly diverted and tampered with over 53 vials of fentanyl in medication vials intended for the use of patients in and around the Roanoke, VA area.

Signed and sworn to this 14 day of February, 2020



Darren C. Petri
Special Agent

Subscribed and sworn to before me this 14th day of February, 2020



The Honorable Pamela Meade Sargent
United States Magistrate Judge